

REMARKS

Claims 1, 8, 16, 32, 33 and 41 are currently amended. Claim 2 is canceled without prejudice. Claims 21-27 were previously canceled without prejudice. Claims 9, 10, 28-30, 38 and 39 were withdrawn from consideration. Applicant notes that independent claim 34 is allowed and respectfully requests reinstatement of withdrawn dependent claims 38 and 39. Claims 1, 3-20 and 28-43 are pending in the application as amended. The amendments do not present new matter. *See, e.g.*, claim 2 as filed. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Allowed Claims

Applicant kindly acknowledges that claims 34-37, 40 and 41 are allowed. Claim 41 is amended for better form by adding “to” before “form.” Applicant respectfully submits that claim 41 remains allowed given the nature of the amendment.

II. Allowable Claims

Applicant also kindly acknowledges that dependent claims 32 and 33 would be allowable if rewritten in independent form to include the elements and limitations of respective independent claims 13 and 16. In accordance with this indication of allowability, claim 32 is amended to include the elements and limitations of claim 13, and claim 33 is amended to include the elements and limitations of claim 16.

III. Withdrawn Rejection / Status of Claims / Rejection Based on Gadsby

Page 2 of the Office Action refers to “Claims 1-7, 11-20, 31-37, 40 and 41” as allegedly being anticipated by U.S. Patent No. 5,309,909 to Gadsby (“Gadsby”), but page 11 of the Office Action states that claims 34-37, 40 and 41 are allowed and claims 32 and 33 would be allowable if rewritten in independent form, pages 2-4 of the Office Action do not discuss claims 8 and 13-18, but page 4 addresses claim 42.

Accordingly, Applicant’s understanding is as follows: claims 34-37, 40 and 41 are allowed, claims 32 and 33 are allowable if rewritten in independent form, the rejection of claims 8 and 13-18 as allegedly being anticipated by Gadsby is withdrawn, and it is alleged that claims 1, 3-7, 11, 12, 19, 20, 31 and 42 are anticipated by Gadsby.

Clarification is respectfully requested if Applicant is not correct.

IV. Claims 1, 3-7, 11, 12, 19, 20, 31 and 42 Are Novel Over Gadsby

Independent claim 1 and dependent claims 3-7, 11, 12, 19, 20, 31 and 42 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gadsby. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Applicant respectfully traverses the rejection.

The Office Action alleges that the electrode 12 described by Gadsby is a “carrier moveable between an unstressed state and a deflected and stressed state” as recited in claim 1 and further alleges that penetration tines 18 are “carried/disposed on the carrier (12)” and adhesive layer 22 “certainly secures itself to the tissue and the carrier (12)...” Applicant notes again that Gadsby refers to the electrode 12 as the entire device (as indicated by arrow). In view of claim 1, a tissue stimulation element must be “supported by the carrier” and a tissue engagement device must be “carried by the carrier.” However, since the electrode 12 is the entire device, the Office Action essentially alleges that the penetration tines 18 are carried / disposed on the “entire device” (the electrode 12) when in fact they project from an inner surface of a dome 16, and essentially alleges that component 22 (which is a conductive pad and not an adhesive layer) secures itself to the “entire device” (the electrode 12). Office Action (p. 10); Gadsby (Fig. 2; col. 3, lines 58-59) (conductive pad 22); col. 4, lines 28-29 (conductive pad 22); col. 6, line 9 (conductive pad 22).

Nevertheless, Gadsby does not anticipate any rejected claim since it is conceded in the Office Action that Gadsby fails to disclose, teach or suggest “a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue by piercing tissue and to secure the carrier to the tissue in the deflected and stressed state” as recited in claim 1. Office Action (p. 10). It is then alleged that the “adhesive layer (22) forms the tissue engagement device.” Office Action (p. 10). As noted above, component 22 is a conductive pad, whereas component 20 is an adhesive support structure. However, neither the conductive pad 20 nor the adhesive support structure 22 secures itself to tissue by piercing tissue. Office Action (p. 10); Gadsby (Fig. 2; col. 3, lines 58-59; col. 4, lines 28-29) (adhesive support structure 20 and conductive pad 22 are free of any structure capable of piercing tissue).

Moreover, Gadsby fails to disclose, teach or suggest “a tissue stimulation element supported by the carrier and capable of transmitting energy” as recited in claim 1. It is alleged in

the Office Action that penetration tines 18, individually or collectively, form a tissue stimulation element, but Gadsby is silent as to penetration tines transmitting energy. Instead, Gadsby explains that the purpose of the tines 18 is to penetrate tissue in order to reduce skin impedance, and that they are plastic. Gadsby (col. 4, lines 61-65). Further, Gadsby describes an electrode that is used for monitoring and receiving biopotentials without expensive equipment or labor intensive preparation. Gadsby (col. 3, lines 46-48).

Gadsby, therefore, does not anticipate independent claim 1. Dependent claims 3-7, 11, 12, 19, 20, 31 and 42 incorporate the elements and limitations of independent claim and, therefore, are also believed novel over Gadsby.

Additionally, the Office Action alleges that dependent claim 42 is anticipated by Gadsby. Claim 42 recites *inter alia* “the tissue engagement device having a sharpened end for piercing tissue.” It is alleged that the “adhesive layer 22” (which is a conductive pad) is the “tissue engagement device” as recited in the claims, but neither the adhesive support structure 20 nor the conductive pad 22 has a sharpened end for piercing tissue. Gadsby (Fig. 2). Thus, Gadsby cannot anticipate claim 42.

V. Claims 13-15 Are Novel Over Tetzlaff

Independent claim 13 and dependent claims 14 and 15 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff *et al.* (hereafter “Tetzlaff”). Applicant respectfully traverses the rejection since Tetzlaff fails to disclose, teach or suggest means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a “single side” of the tissue structure and pressing the stimulation element against the “single side” of the tissue structure as recited in claim 13. Instead, Tetzlaff describes a forceps which, as is well known by persons skilled in the art, function by clamping tissue between inner surfaces of two clamp members. Tetzlaff (Figs. 8-11; col. 3, line 59 (grasp a vessel 150 “therebetween”)). For reference, see also Patent No. 6,162,220 to Nezhat (col. 6, lines 20-21 (tissue grasped between two opposed surfaces)).

Accordingly, the forceps described by Tetzlaff does not engage a “single side” of tissue or press a stimulation element against a “single side” of tissue given the manner in which the forceps device described by Tetzlaff functions. In this regard, while acknowledging that the rejection under 35 U.S.C. §102(b) cannot stand, Tetzlaff also teaches away from claims 13-15.

Applicant, therefore, respectfully requests that the rejection of independent claim 13 be withdrawn since Tetzlaff does not anticipate, and is not related to, means that operate by engaging and pressing a stimulation element against a “single side” of a tissue structure. Dependent claims 14 and 15 incorporate the elements and limitations of independent claim and, therefore, are also believed novel over Tetzlaff.

VI. Status of Claims / Rejection Based on Tetzlaff and Nezhat

Page 5 of the Office Action refers to “Claims 1, 8 and 42” as allegedly being unpatenable over Tetzlaff in view of U.S Patent No. 6,162,220 to Nezhat (“Nezhat”), but pages 12-13 of the Office Action also discuss claims 16-20. Accordingly, Applicant’s understanding is that claims 1, 8, 16-20 and 42 stand rejected under U.S.C. §103(a) as allegedly being unpatentable over Tetzlaff in view of Nezhat. Clarification is respectfully requested if Applicant is not correct.

VII. Claims 1, 8, 16-20 and 42 Are Patentable Over Tetzlaff and Nezhat

Independent claims 1, 8 and 16 and respective dependent claims 17-20 and 42 apparently stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tetzlaff in view of Nezhat.

With regard to claim 1, it is conceded in the Office Action that Tetzlaff fails to disclose a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state and wherein the tissue engagement device comprises a sharpened end for piercing tissue. Office Action (p. 5). With regard to claim 8, it is conceded in the Office Action that Tetzlaff fails to disclose first and second tissue piercing members carried by the carrier to secure the carrier to the tissue in the deflected and stressed state. Office Action (p. 6). With regard to claim 16, it is conceded in the Office Action that Tetzlaff fails to disclose an anchor securing the surgical apparatus to the tissue by piercing the tissue. Office Action (p. 7). Nezhat is cited for the limited purpose of allegedly disclosing penetrating elements. Office Action (p. 5). It is alleged that it would have been obvious to modify the structure described by Tetzlaff to provide needle / teethlike penetrating elements. Office Action (pp. 5-7).

Applicant respectfully submits that Tetzlaff teaches away from claims 1, 8 and 16 and teaches away from substantial modifications involving needle or teethlike penetrating elements

as alleged in the Office Action since Tetzlaff describes a structural configuration that is the opposite of the configuration recited in claims 1, 8 and 16. Specifically, Tetzlaff shows electrodes 110, 120 having smooth surfaces (Tetzlaff, Fig. 2) and explains that the electrodes have seal surfaces, which are preferably “relatively flat to avoid current concentrations at sharp edges and to avoid arcing between high points.” Tetzlaff (col. 7, lines 1-17; col. 7, line 66 - col. 8, line 1) (emphasis added). Modifying the device configuration described by Tetzlaff to include needle / toothlike penetrating elements (Office Action, p. 7) would destroy or eliminate the flat or smooth electrode surfaces that are necessary to avoid arcing and current concentrations at sharp edges as described by Tetzlaff. Thus, the Office Action allegations contradict and are not supported by Tetzlaff.

Moreover, while the Office Action recites an allegation relating to pressing a stimulation element against tissue (Office Action, p. 6), it is implicitly conceded in pages 5-7 of the Office Action that dependent claim 2, which depends from independent claim 1, is novel and non-obvious over Tetzlaff and Nezhat. Claim 1 is amended to include the limitations of dependent claim 2. Claim 8 is amended to recite *inter alia* “wherein the carrier is configured to press the tissue stimulation element against tissue when in the deflected and stressed state; and claim 16 is amended to recite *inter alia* “the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and to press the stimulation element against the tissue when the anchor is in a deflected and stressed state.”

Dependent claims 17-20 and 42 depend from respective claims 1 and 16 and, therefore, are also believed patentable over the cited references.

In view of the above remarks, Applicant respectfully requests that the rejection of claims 1, 8, 16-20 and 42 under 35 U.S.C. §103(a) be withdrawn.

VIII. Claim 43 Is Patentable Over Tetzlaff and Nezhat

Dependent claim 43 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Tetzlaff (as applied to independent claim 13) in view of Nezhat. Dependent claim 43 depends from claim 13 and, therefore, is also believed patentable over Tetzlaff and Nezhat in view of the above remarks. Further, Applicant believes that the rejection of claim 43 was inadvertently duplicated on pages 8-9 of the Office Action.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

VISTA IP LAW GROUP LLP

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By: / Gary D. Lueck /

Gary D. Lueck
Reg. No. 50,791
Attorneys for Applicant

12930 Saratoga Avenue, Suite D-2
Saratoga, California 95070
Telephone: (408) 777-2905
Facsimile: (408) 877-1662